NOV 2 2012

510(K) SUMMARY K120909

EC 2.7 Endoscopic Cutter - 510(k) Summary

Submitter:	Medtronic Advanced Energy, LLC
Contact:	Martin J. Leighton Tel: 603-742-1515 Fax: 603-742-1488
Date Summary Prepared:	November 2, 2012
Device Trade Name:	EC 2.7 Endoscopic Cutter
Common Name:	Electrosurgical cutting and coagulation accessories and Endoscopic electrosurgical unit and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Code:	21 CFR §878.4400
Product Code	GEI
Equivalent Device(s):	Olympus CD-6C-1 Coagulation Electrode (K971321)
Device Description:	The EC 2.7 Endoscopic Cutter is a disposable, single-patient-use monopolar RF (radio-frequency) surgical endotherapy device intended to be inserted through the working channel of a flexible bronchoscope. The EC 2.7 Endoscopic Cutter is terminally sterilized via ETO. It is comprised of a separately packaged, cylindrically shaped, disposable monopolar cutting and coagulation electrode affixed to the distal end of a polymeric, flexible multi lumen shaft , and a separately packaged, single-patient-use, electrical adaptor with cabling, intended for connection to the monopolar output port of a Covidien® Corporation, ValleyLab™ Force FX™ or FX-C Electrosurgical Generator. The ValleyLab™ Force FX™ was cleared to market via 510(k) K944602.

	The Endoscopic Cutter System is intended to be energized for use by the foot-switch accessory supplied with the electrosurgical generator. The EC 2.7 has an active length of approximately 750 mm and a maximum diameter crossing profile of 2.68 mm. It is sized such that may be delivered through the working channel of a flexible bronchoscope 2.8 mm diameter working channel and working length of 600 mm.
Intended use:	The EC 2.7 Endoscopic Cutter is intended to be inserted through the working channel of a flexible bronchoscope having an instrument channel diameter of 2.8 mm minimum, a working length of 600 mm, activated by a foot-switch connected to a qualified electrosurgical generator, and utilized in electrosurgical procedures involving removal/cutting of soft tissues (excision, incision, vaporization, ablation) while also providing electrosurgical coagulation and hemostasis.
Indications for Use:	The EC 2.7 Endoscopic Cutter is a single use electrosurgical instrument designed to be used with flexible bronchoscopes and qualified electrosurgical units. It is indicated for cutting of soft tissue obstructions in upper airways and tracheobronchial tree, and provision of electrosurgical hemostasis during such procedures.
Non-clinical Performance Data:	Performance testing per standardized methods and internal test protocols, including bench testing, human cadaveric studies and *in vivo* animal data collection, was conducted and provides support that the EC 2.7 Endoscopic Cutter is substantially equivalent to currently marketed predicate devices. Additional comparative performance testing was conducted inconsideration of other devices with similar intended indications and intended use. Non-clinical performance test protocols and reports of results are identified in Sections 14 through 19 of this 510(k) submission. Test protocols and reports of results demonstrate that, in consideration of its intended and indications for use, the performance, design, labeling, packaging and sterilization of the EC 2.7 Endoscopic Cutter is compliant with the following standards: • ANSI/AAMI ISO 11135-1:2007: Sterilization of health care products - Ethylene Oxide - Part 1: Requirements for the development, validation and

routine control of a sterilization process for medical devices
- ISO 11607-1:2006, Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier
- ISO 11607-2:2006: Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes, including Annex B (informative) listing of standardized test methods and procedures
- ASTM F1980-07; Shelf-life and accelerated aging techniques for standard evaluation of packaging performance
- ISO 10993-4:2002, Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity.
- ISO 10993-7:2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2002 (A1:2006), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- ANSI AAMI ES 60601-1: 2005 3rd Edition: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements for Safety Collateral Standard Electromagnetic Compatibility. Requirements and Tests.
- IEC 60601-2-2:2009, 5th Edition, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
- IEC 60601-2-18:2009, 3th Edition, Particular requirements for the basic safety and essential performance of endoscopic equipment

Clinical Performance Data: Clinical data was not necessary to support that the EC 2.7 is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Medtronic Advanced Energy, LLC
% Mr. Martin J. Leighton
Senior Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Letter Dated: November 2, 2012

Re: K120909
Trade/Device Name: EC 2.7 Endoscopic Cutter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 25, 2012
Received: October 26, 2012

Dear Mr. Leighton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120909

Device Name: EC 2.7 Endoscopic Cutter

Indications For Use: *The EC 2.7 Endoscopic Cutter is a single use electrosurgical instrument designed to be used with flexible bronchoscopes and qualified electrosurgical units. It is indicated for cutting of soft tissue obstructions in upper airways and tracheobronchial tree, and provision of electrosurgical hemostasis during such procedures.*

Prescription Use _X_ (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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